

REMARKS

Claims 1, 3-13, 36-65, 73-74, 77-79 and 132-168 were pending. Claims 1, 3-13, 36-38, 49-56, 58-65, 73-74, 77-79, 132-159 and 163-168 were withdrawn. Applicants cancelled claims 43 and 46 and amended claims 39, 40, 45, 160 and 162. Accordingly, claims 39-42, 44-45, 47-48, 57, and 160-162 are being examined.

The amendment to the first full paragraph of the specification is merely to update the status of the priority documents.

Support for the amendments to claims 39, 40, 45, 160 and 162 can be found in the specification as originally filed. Accordingly, these changes do not involve new matter and their entry is respectfully requested.

The amendment made to claim 40 merely removes the recitation of the term "neurogenic".

The amendment made to claim 45 is merely to correct the typographical error.

Support for amended claim 39 may be found in the specification at page 6, lines 7-35; page 12, lines 14-22; page 18, lines 18-30; and page 19, lines 1-20.

Support for amended claim 160 may be found in the specification at page 2, line 26; page 6, lines 7-35; page 12, lines 14-22 and lines 29-32; and page 20, lines 13-18.

Support for amended claim 162 may be found in the specification at page 7, lines 1-9.

Entry of these amendments and the foregoing remarks in the file of the above-captioned patent application is respectfully requested.

ELECTION/RESTRICTIONS

The Examiner acknowledges Applicants election of the invention of Group III (claims 39-48, 57 and 160-162) with traverse. The requirement is made final.

PRIORITY

The Office takes the position that claims 39-48 and 57 are granted a filing date of March 9, 2004, since reference to the priority applications does not appear in the first paragraph of the specification.

Applicants respectfully disagree.

As originally filed, Applicants amended the specification to include reference to the priority of the subject application as indicated in the transmittal sheet submitted with the patent application (attached herewith as Exhibit 1). Applicants amended the application to indicate that the subject application is a divisional application of U.S. Serial No. 09/936,665, filed September 10, 2001, which is a 35 U.S.C. §371 of PCT Application No. PCT/US00/06232 filed March 10, 2000, which claims the priority of U.S. Serial No. 60/123,711 filed March 10, 1999 and U.S. Serial No. 60/162,462 filed October 29, 1999.

Accordingly, since reference to the priority applications was added to the specification as originally filed, the pending claims should be granted a priority date of March 10, 1999.

REJECTION UNDER 35 U.S.C. §102(b)

Zuk et al. 2002

At page 5 of the Office Action, the Office rejects claims 39-42, 44-45, 47 and 57 under 35 U.S.C §102(b) as allegedly anticipated by Zuk 2002.

Applicants respectfully disagree.

Since Applicants properly claimed the priority of the parent applications as indicated above, the pending claims of the subject application are entitled to a priority date of March 10, 1999. The Zuk reference was published on December 2002 and thus is not prior art. Therefore, this reference cannot form the basis for an anticipation rejection under §102(b). Accordingly, Applicants respectfully request that the Office reconsider and withdraw the rejections to claims under 35 U.S.C. §102(b).

Wilkison et al. (US 2001/0033834)

At page 6 of the Office Action, the Office rejects claims 39, 40, 43, 47, 48 and 57 under 35 U.S.C §102(b) as allegedly anticipated by Wilkison US 2001/0033834.

Applicants respectfully disagree.

Since Applicants properly claimed the priority of the parent applications as indicated above, the pending claims of the subject application are entitled to a priority date of March 10, 1999.

The Wilkison reference's earliest priority date is February 26, 2000. In contrast, Applicants are entitled to the priority of U.S. Serial No. 60/123,711, filed March 10, 1999

and U.S. Serial No. 60/162,462, filed October 29, 1999. Specifically, support for the pending claims may be found as follows:

Independent claim 39:

- a. U.S. Serial No. 60/123,711, filed March 10, 1999: page 6, second full paragraph, lines 4-6; page 22, second full paragraph, lines 1-2; and originally filed claims 29, 37, 41 and 48.
- b. U.S. Serial No. 60/162,462, filed October 29, 1999: page 28, second full paragraph, lines 3-6; page 30, second full paragraph, lines 1-2; and pages 34-35.

Independent claim 160:

- a. U.S. Serial No. 60/123,711, filed March 10, 1999: page 6, second full paragraph, lines 4-6; page 22 second full paragraph, lines 1-2; and originally filed claims 29, 37, 41 and 48.
- b. U.S. Serial No. 60/162,462, filed October 29, 1999: page 28, second full paragraph, lines 3-6; page 30, second full paragraph, lines 1-2; and pages 34-35.

Accordingly, Applicants' earlier priority date precludes Wilkison as a prior art reference. Therefore, this reference cannot form the basis for an anticipation rejection under §102(b). Accordingly, Applicants respectfully request that the Office reconsider and withdraw the rejections to claims under 35 U.S.C. §102(b).

Ailhaud et al. 1983

At page 7 of the Office Action, the Office rejects claim 160 under 35 U.S.C §102(b) as allegedly anticipated by Ailhaud 1983.

Applicants respectfully disagree.

The legal standard for anticipation was described above.

Ailhaud et al. (1983) teaches methods for culturing an established preadipocyte cell line, ob17, to induce differentiation into mature adipocytes. However, Ailhaud (1983) does not expressly teach adipose-derived stem cells, let alone a mixed population of adipose derived stem cells which are multipotent, i.e., a stem cell that reproduces itself and at least two further differentiated progeny cells from distinct developmental lineages. Ailhaud does not inherently teach a mixed population of adipose derived stem cells, because the preadipocyte cell line, ob17, is not a stem cell or a mixed population thereof. Instead, ob17 is a cell line in a stage of differentiation that is committed to being an adipocyte (Ailhaud at page 125, first sentence of summary and the sentence bridging the left and right columns).

Since Ailhaud (1983) does not teach each and every element of the isolated adipose-derived stem cell, or a population of the claimed stem cells, of the claimed methods, the teachings in this reference cannot anticipate the methods for differentiating the isolated adipose-derived stem cells of the claimed methods.

REJECTION UNDER 35 U.S.C. §102(e)

At page 7 of the Office Action, the Office rejects claim 162 under 35 U.S.C §102(e) as allegedly anticipated by Gimble U.S. Patent No. 6,555,374 ('374 patent).

Applicants respectfully disagree.

Since Applicants properly claimed the priority of the parent applications as indicated above, the pending claims of the subject application are entitled to a priority date of U.S. Serial No. 60/123,711, filed March 10, 1999.

The earliest priority date of the '374 patent is August 19, 1999. In contrast, Applicants are entitled to the priority of U.S. Serial No. 60/123,711, filed March 10, 1999. Accordingly, Applicants' earlier priority date precludes Gimble as a prior art reference. Therefore, this reference cannot form the basis for an anticipation rejection under §102(e). Accordingly, Applicants respectfully request that the Office reconsider and withdraw the rejections to claims under 35 U.S.C. §102(e).

REJECTION UNDER 35 U.S.C. §103(a)

Wilkison et al. (US2001/0033834), Halvorsen et al. (US 6,429,013), Halvorsen et al. (US2002/0119126) and Gimble et al. (US 6,555,374)

At page 8 of the Office Action, the Office rejects claims 39-48, and 57 under 35 U.S.C §103(a) as allegedly unpatentable over Wilkison (US 2001/0033834), in view of Halvorsen (US Patent No. 6,429,013) ('013 patent), Halvorsen (US 2002/0119126), and Gimble '374 patent.

Applicants respectfully disagree.

As discussed above, Wilkison is disqualified as a proper prior art reference. Since Wilkison, the primary reference, is disqualified as a prior art reference, Wilkison cannot be combined with the Halvorsen references and Gimble '374 patent, and thus the combination fails. For this reason, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 39-48, and 57.

Moreover, even if Wilkison is not disqualified as a prior art reference, Gimble is disqualified as a proper prior art reference for the reasons described above. Since Gimble is disqualified as a prior art reference, Gimble cannot be combined with Wilkinson and the Halvorsen references, and thus the combination fails. For this additional reason, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 39-48, and 57.

Ailhaud et al. (1983) and Golde et al. (US 4,438,032)

At page 10 of the Office Action, the Office rejects claims 160-161 under 35 U.S.C §103(a) as allegedly unpatentable over Ailhaud 1983 in view of Golde (US Patent No. 4,438,032) ('032 patent).

Applicants respectfully disagree.

The burden is on the Examiner to establish a *prima facie* case of obviousness by showing that the prior art would have taught or suggested the claimed invention to one of ordinary skill in the art, and that one of ordinary skill in the art would reasonably expect that the method suggested by the references would be successful¹. The Examiner must provide evidence that both the suggestion to modify the prior art method and the reasonable expectation of success can be found in the prior art². In addition, the prior art must teach or suggest all of the claim limitations³.

As discussed above, Ailhaud discloses preadipocyte cell line. Ailhaud did not disclose or suggest adipose derived stem cells.

¹ *In re Clinton*, 527 F.2d 1226, 1228, 188 USPQ 365, 367 (CCPA 1976).

² *In re Gangadharam*, 889 F.2d 1101, 13 USPQ2d 1568, 1569 (Fed. Cir. 1989); *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991).

³ *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

The '032 patent teaches a cell line (Mo) which has been established with spleen cells from a patient with a T-cell variant of hairy-cell leukemia ('032 patent at column 2, lines 45-60). The Mo cells grow and exhibit the morphology of relatively mature T-lymphoblasts (column 7, lines 26-28). The cells constitutively produce a wide variety of proteins, including growth factors, such as colony stimulating factor, useful for the growth of granulocyte-macrophage colonies in vitro and erythroid-potentiating activity, which is capable of potentiating the formation of both large and small human erythroid colonies in vitro; human immune interferon, neutrophil migration-inhibition activity, as well as other polypeptides produced by T-lymphoblast cells many of which are secreted and isolatable from the medium.

The '032 patent does not teach or suggest what the primary reference fails to teach, namely, adipose derived stem cells. Accordingly, the combination of the Ailhaud reference and the '032 patent, does not render obvious the claimed methods.

REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH

At page 12 of the Office Action, the Office rejects claim 39 under 35 U.S.C. §112, first paragraph because the specification, "while being enabling for differentiation of adipose-derived stem cells in some morphogenic medium such as adipogenic, osteogenic, chondrogenic, myogenic and embryonic, does not reasonably provide enablement for differentiation of adipose-derived stem cells into any cell type in any morphogenic medium."

Applicants respectfully disagree.

However, in order to further the prosecution of the subject application, Applicants have amended the claims to recite such medium.

In view of the claim amendments, Applicants respectfully request that the Office reconsider and withdraw the various grounds for objection and rejection set forth in the Office Action.

OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTION

At page 15 of the Office Action, the Office provisionally rejected claims 160-162 under 35 U.S.C. §101 as claiming the same invention as that of claims 35-37 of U.S. Serial Nos. 10/845,315 and 10/740,315. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

In response, Applicants respectfully point out that this issue is not ripe. Applicants will revisit this issue at the appropriate time, i.e., when the Patent Office allows overlapping claims in the subject application.


CONCLUSION

If a telephone interview would be of assistance in advancing the prosecution of the subject application, Applicants' undersigned attorney invites the Examiner to telephone her at the number provided below.

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No fee, other than the \$510.00 extension fee, is deemed necessary in connection with the filing of this Amendment. If any further fee is necessary, the Patent Office is authorized to charge any additional fee to Deposit Account No. 50-0306.

Respectfully submitted,

A handwritten signature in cursive script, reading "Sarah B. Adriano". The signature is written in dark ink and is positioned above a horizontal line.

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